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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/805,816	03/13/2001	Mohammad A. Heidaran	07078-030001	6205

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EXAMINER

DI NOLA BARON, LILIANA

ART UNIT PAPER NUMBER

1615

DATE MAILED: 07/03/2002 9

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary

09/805,816

Applicant(s)

HEIDARAN ET AL.

Examiner

Art Unit

Liliana Di Nola-Baron

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 March 2001.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

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Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in-

(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or

(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

2. Claims 1-19 are rejected under 35 U.S.C. 102(e) as being anticipated by Heidaran et al.

The claimed invention refers to methods for inducing or enhancing chondrogenesis comprising exposing cells to compositions comprising collagen and BMP-4 or collagen, BMP-4 and hyaluronate, or collagen, BMP-4, hyaluronate and GDF-5 and to compositions comprising collagen and BMP-4 or collagen, BMP-4 and hyaluronate or collagen, BMP-4, hyaluronate and GDF-5 .

Heidaran et al. discloses collagen-polysaccharide matrices, and preferably collagen-hyaluronic acid matrices containing BMPs and GDFs for the treatment of bone tumors and teaches that the collagen used in the invention is Type I or Type II collagen (See e.g., cols.1-2). Heidaran et al. teaches that the matrices can be used in vitro and in vivo and can be administered by implantation, direct application or injection (See e.g., col. 6, lines 62-67).

The compositions and their medical applications provided by Heidaran et al. meet the limitations of claims 1-19 of the instant application, as they contemplate compositions comprising a

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collagen-hyaluronate matrix comprising BMPs and GDFs and methods comprising exposing the cells to said compositions. Thus, Heidaran et al. anticipates the claimed invention.

3. Claims 1-4 and 12-15 are rejected under 35 U.S.C. 102(e) as being anticipated by Hattersley et al. (U.S. Patent 5,902,785).

Hattersley et al. provides compositions for the induction of cartilaginous tissue formation and tissue repair, comprising BMP-4 (See e.g., cols. 1-2), and a matrix comprising collagen and a sequestering agent, such as hyaluronic acid (See e.g., col. 7, line 51 to col. 8, line 65).

The compositions disclosed by Hattersley et al. and their use meet the limitations of claims 1-4 and 12-15 of the instant application, as they contemplate compositions comprising collagen and BMP-4 or collagen, BMP-4 and hyaluronate, and methods comprising exposing cells to said compositions. Thus, Hattersley et al. anticipates the claimed invention.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 1-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Adams et al. (U.S. Patent 5,118,667).

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Adams et al. discloses a method for stimulating new bone formation comprising administering a bone growth factor, such as TGF- β (which includes GDFs) and BMP (See e.g., col. 3, lines 26-38). Adams et al. teaches that the methods and compositions of the invention are useful for treating bone fractures, defects and disorders (See e.g., col. 6, lines 52-59). Adams et al. teaches that the compositions may be implanted at the site in a sustained-release carrier, which includes collagen matrices (See e.g., col. 7, lines 7-24). Adams et al. teaches that the composition of the invention can be coated on implant devices and the viscosity of the coating solution can be increased by adding hyaluronate (See e.g., col. 7, lines 40-58).

Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to apply the teachings of Adams et al. to devise methods and compositions for inducing chondrogenesis, since the method disclosed by Adams et al. contemplates administering compositions comprising bone growth factors in carrier matrices to regenerate bone tissue. The expected result would have been successful methods and compositions for the regeneration of cartilage. Because of the teachings of Adams et al., that compositions comprising bone growth factors in a collagen matrix comprising hyaluronate are effective in stimulating new bone formation, one of ordinary skill in the art would have a reasonable expectation that the methods and compositions claimed in the instant application would be successful. Therefore the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

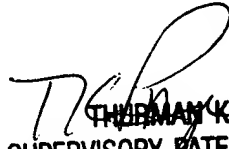
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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Liliana Di Nola-Baron whose telephone number is 703-308-8318. The examiner can normally be reached on Monday through Thursday, 5:30AM-4:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on 703-308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3592 for regular communications and 703-305-3592 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 308-1234/ 1235.

June 19, 2002


THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

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